K102608

SECTION 3 – 510(k) SUMMARY

OCT 08 2010

DATE PREPARED: August 27, 2010 (original submission)
DATE REVISED: October 8, 2010

OWNER/OPERATOR:

Firm:	Hologic, Inc.	Contact Name: Alyssa M. Lobo
Address:	6100 Technology Center Drive Indianapolis, IN 46278	Title: Senior Quality and Regulatory Consultant *(a full-time employee of Hologic, Inc.)*
Phone Number:	317-344-7500	Phone Number: 317-344-7532
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Registration Number:	3003862400	

DEVICE NAME:

Classification Name:	Marker, Implantable Radiographic
Common/Usual Name:	Tissue Site Marking System
Proprietary Name:	SecurMark Biopsy Site Marking System
Device Class:	Class II
Description:	Implantable Clip
Number:	NEU
21 CFR Ref:	878.4300
Performance Standard:	None established

PREDICATE DEVICES:

510(k) Number	Device Name	Device Manufacturer	Location
K072913	SecurMark Biopsy Site Identification System	Hologic, Inc. (formerly Suros Surgical Systems, Inc.)	Indianapolis, IN
K062528	Tissue Site Marking System	Hologic, Inc. (formerly Suros Surgical Systems, Inc.)	Indianapolis, IN

Description of the Device

The SecurMark Biopsy Site Marker is a sterile, single patient use device comprised of a single, biocompatible titanium or stainless steel marker surrounded by a bioabsorbable suture-like material and deployment device.

The deployment device is a hand-held device that delivers the marker from the distal tip. The deployment device consists of a flexible cannula, handle, flexible push rod, and plunger. The marker is located at the distal end of the deployment device.

Indications for Use and Intended Use

Indications for Use
The Tissue Site Marking System is indicated for the permanent radiographic marking of sites in soft tissue.

Intended Use
The SecurMark Biopsy Site Marking System is intended for use with the manual method of deployment. It can be visualized under various imaging modalities such as ultrasound, x-ray, magnetic resonance, direct visualization, and others. This system is intended for single patient use only.

Comparison of 510(k) Cleared Tissue Site Marking Systems

The SecurMark Biopsy Site Marker that is the subject of this submission is comprised of two 510(k) cleared devices. The first is an implantable component, covered by K062528, held by Hologic, Inc. which is composed of a bioabsorbable component and a permanent marking component (316 stainless steel or titanium). The second is a deployment device, covered by K072913, held by Hologic, Inc. The subject of this 510(k) is similar to the predicate devices in the following areas: Indications for Use, Intended Use, Scientific Technology, biocompatibility, sterilization (dose, method, and SAL), marker materials, deployment device materials, packaging materials, deployment device manufacturing site, deployment device manufacturing methods, deployment device dimensions, marker dimensions, shelf life, and deployment method. The product is also supplied sterile for single patient use, like the predicate devices.

The subject of this 510(k) is different from the device cleared in K072913 in that the permanent marker material in that 510(k) was listed only as titanium. The subject of this 510(k) is different from the device cleared in K062528 in that the deployment device is constructed from different materials. The shapes of the permanent marking components in this submission are different from the shapes of the marking components that were cleared in both K072913 and K062528. All other aspects of the subject of this 510(k) submission are the same as the legally marketed devices.

Non-Clinical Evaluation

The devices that are the subject of this submission have been evaluated through a number of tests, or prior test results for predicate devices apply to the devices that are subject of this submission. Testing, evaluations, and/or analyses have been performed for: simulated use, gross evaluation, shelf life, tensile testing, functionality at specified temperatures, MRI compatibility and artifacts, X-ray distinctive visualization, calcification distinguishability, sterilization validation, biocompatibility, tolerance analyses, and viscosity and moisture.

The devices met or exceeded the acceptance criteria for all evaluations.

Conclusion

Based on the information presented in this Special 510(k) submission, the SecurMark Biopsy Site Marking System is substantially equivalent to the presently marketed Hologic, Inc. Tissue Site Marking System (K062528) and the SecurMark Biopsy Site Identification System (K072913).

No new safety or efficacy questions are raised with the SecurMark Biopsy Site Marking System that is the subject of this submission.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Hologic, Inc.
% Ms. Alyssa M. Lobo
Senior Quality and Regulatory Consultant
6100 Technology Center Drive
Indianapolis, Indiana 46278

OCT 0 8 2010

Re: K102608
Trade/Device Name: SecurMark Biopsy Site Marking System
Regulation Number: 21 CFR 878.4300
Regulation Name: Implantable clip
Regulatory Class: Class II
Product Code: NEU
Dated: August 27, 2010
Received: September 13, 2010

Dear Ms. Lobo:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K102608

Device Name: SecurMark Biopsy Site Marking System

Indications For Use: The SecurMark Biopsy Site Marking System is indicated for the permanent radiographic marking of sites in soft tissue.

Prescription Use __X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause for MKM

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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